

**REMARKS/ARGUMENTS**

The Examiner has indicated that Applicant's response filed on September 26, 2008 (Response) was not fully responsive. In particular, Applicant failed to specifically point out the support in the original disclosure for each of the newly presented claim limitations of claim 1 and newly added claims 21-25.

Claim 1 was amended in the Response to add the limitation that validation of the manufacturing process "includes generating an organized set of documents, defining aspects of the process, in conformance with regulatory standards". Applicant submits that this added limitation of claim 1 is fully supported by the original disclosure. *See, for example*, Specification at paragraph 57.

Claim 21 recites that "the requirements are user requirements or functional requirements." The limitation of claim 21 is fully supported by the original disclosure. *See, for example*, Specification at paragraph 49.

Claims 22 and 23 recite what user and functional requirements are, respectively. The limitations of claims 22-23 are fully supported by the original disclosure. *See, for example*, Specification at paragraph 49.

Claims 24 and 25 recite the types of documents or information or content contained in the documents. The limitations of claims 24-25 are fully supported by the original disclosure. *See, for example*, Specification at paragraph 57.

Accordingly, Applicants submit that the Response is fully responsive.

**Conclusion**

In view of the foregoing, Applicants believe that all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Should the Examiner believe that a telephone conference would expedite prosecution of this application, please telephone the undersigned attorney at his number set out below.

Date: January 14, 2009

Respectfully submitted,

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